Message

From: Milbourn, Cathy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=235D8027F05546DBA9897972F0B78419-CMILBOUR]
Sent: 7/20/2022 5:15:46 PM
To: Aruni Soni [aruni.soni@investigatemidwest.org]
CC: EPA Press Office [Press@epa.gov]
Subject: Questions regarding the Seresto Pet Collar Investigation Follow Up

Hello Aruni,

Regarding the letter:

We will review and respond through the appropriate channels.

On background

EPA's Office of Pesticide Programs – which regulates the manufacture and use of thousands of pesticide products (including insecticides, herbicides, rodenticides, disinfectants, sanitizers and more) in the United States – currently has less than 600 full-time employees, down from a high of more than 800 in 2005, and only two veterinarians whose responsibilities extend beyond pet products. More information on the structure and staffing for FDA's Center for Veterinary Medicine can be found at https://www.fda.gov/about-fda/fda-organization/center-veterinary-medicine.

Background Statement

Under the Biden-Harris administration, EPA continues to take unprecedented steps to address concerns related to Seresto pet collars and other pesticide products used on pets. EPA understands and shares the public's concerns about reported incidents with these collars. Pets hold a special place in the hearts of many Americans, and any incidents that jeopardize their safety are concerning and should be addressed.

EPA had previously concluded its review of flumethrin (one of the active ingredients in Seresto) in March of 2020 with the issuance of an Interim Decision. That Decision stated that EPA would consider how to evaluate additional pet incidents for all pet products and future changes could occur based on public feedback and a review of pet incidents as a whole. Under typical statutory re-registration processes and timelines, EPA would typically not be required to re-review this active ingredient until 2035.

However, in April 2021, EPA sent a letter to Elanco and Bayer, the current and former registrants of Seresto pet collars, reiterating their legally required duty under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to report incidents with this product and requiring them to provide additional data on reported adverse effects of Seresto pet collars. This additional information was more extensive than what is routinely reported by pesticide product registrants to EPA's Incident Data System and included a requirement to provide detailed sales data, data on annual incident rates and severity, and any incidents in other countries where the collars are sold.

EPA received the information from these companies in May 2021. To assist with the analysis of the information received as well as the information in the Incident Data System, EPA requested and is receiving consultative support from the Food and Drug Administration Center for Veterinary Medicine (FDA/CVM), which regulates animal drugs, including certain drugs to control fleas and ticks. EPA appreciates the FDA/CVM assistance since they have extensive expertise in animal safety evaluation, post-market monitoring requirements, and existing adverse event reporting infrastructure for the animal drugs FDA regulates. While EPA also evaluates animal safety for some pesticide products, the Agency lacks the resources needed (e.g., staff, expertise, infrastructure, and funding) to evaluate animal safety and conduct on-going monitoring of marketed products. EPA's Office of Pesticide Programs – which regulates the manufacture and use of thousands of pesticide products (including insecticides, herbicides, rodenticides, disinfectants, sanitizers and more) in

the United States – currently has fewer than 600 full-time employees, down from a high of more than 800 in 2005, and only two veterinarians whose responsibilities extend beyond pet products.

With the consultative assistance of FDA, EPA expects to finish its scientific review of incident data and other studies by fall 2022. Upon completing its analysis and assessment, EPA will determine whether these pet collar registrations can still be used safely according to the instructions on the label or if additional safety measures or cancellations are needed for these products.

Additionally, on July 13, 2021, the Agency asked for public comment on a petition from the Center for Biological Diversity requesting EPA cancel the Seresto registration and suspend the registration pending cancellation. EPA is currently reviewing comments received from over 5,400 sources during the public comment period. After completing its evaluation of the incident data, expected in fall 2022, the Agency will respond to the petition and the public comments.

On May 19, 2022, EPA's Office of Inspector General (OIG) announced that it would begin evaluating whether EPA's response to reported incidents of unintended effects from pet collar pesticides was consistent with Section 6(a)(2) of FIFRA. EPA will fully cooperate with the OIG as the Agency works to identify any necessary improvements.
Finally, EPA's staff is working hard to complete registration review interim decisions between 2022 and 2024 for 37 pesticide active ingredients which are registered for use on pets, including, but not limited to, acetamiprid, dinotefuran, fipronil, imidacloprid, and tetrachlorvinphos. The registration review process includes a comprehensive evaluation of risks and may result in label changes or cancellation of specific products to address any identified risks of concern. To see the registration review schedule for pesticides, including those used on pets, visit EPA's website.

From: Aruni Soni <aruni.soni@investigatemidwest.org>
Sent: Wednesday, July 20, 2022 11:30 AM
To: Milbourn, Cathy <Milbourn.Cathy@epa.gov>
Cc: EPA Press Office <Press@epa.gov>
Subject: Re: Questions regarding the Seresto Pet Collar Investigation Follow Up

Thank you for your response. Any chance I hear back by noon today?

On Tue, Jul 19, 2022 at 2:05 PM Milbourn, Cathy <Milbourn.Cathy@epa.gov> wrote:

> Hello Aruni,
>
> Acknowledging your inquiry and deadline.
>
> Regards,
>
> Cathy

From: Aruni Soni <aruni.soni@investigatemidwest.org>
Sent: Tuesday, July 19, 2022 2:51 PM
To: Milbourn, Cathy <Milbourn.Cathy@epa.gov>
Cc: EPA Press Office <Press@epa.gov>
Subject: Questions regarding the Seresto Pet Collar Investigation Follow Up

Hi Cathy,

My name is Aruni Soni and I'm a reporter with Investigate Midwest. We came across a letter from the Chairman of the House Subcommittee on Economic and Consumer Policy to the EPA to take action on their investigation into the Seresto pet collars. We are writing an update on our previous reporting on this issue and had some questions to ask you. If you could respond by 12pm CT tomorrow, that would be great.

Here are my questions:

- What is the EPA's response to the letter by Chairman Raja Krishnamoorthi of the House Subcommittee on Economic and Consumer Policy?

- About the recommendations in the letter:

    - Will the EPA heed the recommendation to commence NOIC proceedings (to evaluate whether the product remains on the market in the long term)? What are the roadblocks/reasons not to take this recommendation? How will the EPA deal with Elanco's refusal to admit any link between their product and pet fatalities?

    - Will the EPA update guidelines for companion animal and clinical studies as the letter recommends? What are the roadblocks/reasons not to?

    - Will the EPA improve its data collection system as recommended in the letter? What are reasons to/not to?

- Why has there continually been a push to collect more data instead of taking action on the Seresto collars?

Thank you for your time.

Aruni Soni

Reporter at Investigate Midwest

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Aruni Soni
Reporter at Investigate Midwest